UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

IN RE: TYLENOL (ACETAMINOPHEN) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	§	**MDL NO. 2436** **2:13-md-02436** **HON. LAWRENCE F. STENGEL**
This Document Relates to: Rana Terry, as Personal Representative and Administrator of the Estate of Denice Hayes, Deceased, Plaintiff, vs. McNEIL-PPC, Inc., McNeil Consumer Healthcare, and Johnson & Johnson, Inc., Defendants.	§	Civil Action No. 2:12-cv-07263

M E M O R A N D U M

Stengel, J. **November 13, 2015**

This case is part of a products liability Multidistrict Litigation (MDL) involving claims of liver damage from the use of Tylenol at or just above the recommended dosage.[1] This is the first "bellwether" scheduled for trial.[2] The plaintiff claims that her

[1] See Master Compl., 13-md-2436, Doc. No. 32. There are close to two hundred other cases included in this MDL, along with several similar cases in New Jersey state court.

sister died of acute liver failure after taking Extra Strength Tylenol and that Defendants Johnson & Johnson and McNeil—the makers of Extra Strength Tylenol—are liable under several legal theories.[3]

The defendants have moved for summary judgment on several of the plaintiff's short form complaint claims. They claim the plaintiff's counts brought under theories of fraud and fraudulent misrepresentation are preempted by federal law. For the reasons explained below, I will deny the defendants' motion.

I. PLAINTIFF'S SHORT FORM COMPLAINT CLAIMS

The plaintiff alleges that Extra Strength Tylenol can cause liver damage at or just above the dose recommended by the defendants. The defendants were allegedly aware of this risk but failed to prevent it. As a result, the plaintiff claims her sister, Denice Hayes, died from acetaminophen-induced acute liver failure.[4]

As part of this MDL, Mr. Terry asserted several claims in her "short form complaint"—a form document used by plaintiffs wishing to be included in the MDL. See Short Form Complaint, Doc. No. 28. The short complaint included claims for:

- Count I: Strict Liability,
- Count II: Breach of Implied Warranty of Merchantability,
- Count III: Breach of Implied Warranty of Fitness for a Particular Purpose,

---

[2] A "bellwether" case is a test case. "Bellwether" trials should produce representative verdicts and settlements. The parties can use these verdicts and settlements to gauge the strength of the common MDL claims to determine if a global resolution of the MDL is possible. See FEDERAL JUDICIAL CENTER, MANUAL FOR COMPLEX LITIGATION, FOURTH EDITION 360 (2004); DUKE LAW CENTER FOR JUDICIAL STUDIES, MDL STANDARDS AND BEST PRACTICES 16-21 (2014).

[3] See Compl., 12-cv-07263, Doc. No. 1.

[4] See Plaintiff's Fact Sheet (Doc. No. 49-8, Ex. G); Denice Hayes Death Certificate (Doc. No. 45, Ex. A). See also R. Hayes Dep. at 76, 171 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

- Count IV: Negligent Failure to Warn,
- Count V: Negligent Design Defect,
- Count VI: Negligence,
- Count VII: Negligent Misrepresentation,
- Count VIII: Breach of Express Warranty,
- Count IX: Fraud,
- Count X: Alabama Code § 8-19-1 (Alabama Deceptive Trade Practices Act),
- Count XI: Fraudulent Concealment,
- Count XIII: Punitive Damages,
- Count XIV: Discovery Rule & Tolling,
- Count XV: Wrongful Death, and
- Count XVI: Survival Action.

The defendants moved for summary judgment on Counts I, II, III, IV, V, VII, VIII, IX, X, XI, XIII, and XVI based on various legal theories. The defendants also moved for summary judgment on Counts IV, V, and XV in separate motions. I entered orders with a decision on each of these motions. The parties stipulated that Counts I, II, III, VIII, XIII (based on a warranty theory), X, and XVI should be dismissed. See Stipulation, Jun 17, 2015 (Doc. No. 86). The plaintiff conceded that a separate "negligent marketing" claim would not be valid, but the parties disagree about whether evidence of marketing tactics can be presented at trial. See id.

For the purposes of this motion regarding claims in the short form complaint, only Counts IX: Fraud and XI: Fraudulent Concealment remain at issue. See id. The defendants move for their dismissal based on theories of preemption.

II. BASIS FOR FRAUD CLAIMS

The plaintiff offers evidence that the defendants knew Extra Strength Tylenol at recommended doses, or doses just above the recommended maximum, could cause liver

damage resulting in death.[5] The majority of acute liver failure cases in the United States are related to the use of acetaminophen.[6] The safety of acetaminophen has been questioned by the medical and scientific community since the 1980s.[7]

Despite this, McNeil and Johnson & Johnson have marketed Extra Strength Tylenol for decades as "the number one doctor-recommended pain reliever" and as a product that is "safe and effective."[8] The plaintiff claims that the defendants' actions in marketing Extra Strength Tylenol as "safe and effective," when they knew it was not, amount to fraud and/or fraudulent concealment by the defendants. She has offered evidence that Denice took Tylenol because she believed it was better and safer than other

[5] See, e.g, McNeil Memorandum November 19, 1987 (Doc. No. 95, Ex. 14); P. Gussin Dep., Dec. 12, 2013 at 198 (Doc. No. 95, Ex. 15).

[6] See FDA, Some Drugs and the Liver Don't Mix, May 2014 (Def. Ex. E, Doc. No. 49-5); Lee, et. al. MEETING REPORT: Acute Liver Failure: Summary of a Workshop, Hepatology 2008; 47:1401-1415 (Doc. No. 95, Ex. 6). See also Larson, et. al., Acetaminophen-Induced Acute Liver Failure: Results of a United States Multicenter, Prospective Study, Hepatology 2005; 42(6):1364-1372 (Doc. No. 95, Ex. 7); Gerald Dal Pan, M.D., Director of Office of Surveillance and Epidemiology, CDER/FDA, Powerpoint, Jun. 29, 2009 (Doc. No. 95, Ex. 21); A. Temple Dep. at 224 (Feb. 18, 2014)(Doc. No. 90, Ex. 1).

These acetaminophen-induced liver injury patients include both people who are intentionally trying to harm themselves (i.e. attempting suicide) and those who take acetaminophen for therapeutic reasons (i.e. to treat physical pain). See FDA Background Package for June 29-30, 2009 Advisory Committee Meeting (Doc. No. 95, Ex. 8); FDA Safety Analysis Power Point, September 19, 2002 (Doc. No. 95, Ex. 11); Lee, W.M., Acetaminophen Toxicity: Changing Perceptions on a Social/Medical Issue, Hepatology 46(4): 966-970 (2007)(Doc. No. 95, Ex. 9); FDA Safety Analysis Power Point, September 19, 2002 (Doc. No. 95, Ex. 11); FDA Memorandum August 15, 2002 (Doc. No. 95, Ex. 17); Gerald Dal Pan, M.D., Director of Office of Surveillance and Epidemiology, CDER/FDA, Powerpoint, Jun. 29, 2009 (Doc. No. 95, Ex. 21); Characterization of Acetaminophen Overdose and Related Hepatotoxic Events, Joint Meeting of the Drug Safety and Risk Management, Nonprescription and Anesthetic and Life Support Drugs Advisory Committees of the FDA, Powerpoint, Jun 29, 2009 (Doc. No. 95, Ex. 21).

[7] See, e.g, Erikkson, L.S., et al., Hepatotoxicity due to repeated intake of low doses of paracetamol, J Intern Med, 1992: 231:567-570 (Doc. No. 95, Ex. 16); FDA Background Package for June 29-30, 2009 Advisory Committee Meeting (Doc. No. 95, Ex. 8); FDA Safety Analysis Power Point, Sept. 19, 2002 (Pl. Ex. 11). See also Lee, W.M., Acetaminophen Toxicity: Changing Perceptions on a Social/Medical Issue, Hepatology 46(4): 966-970 (2007)(Doc. No. 95, Ex. 9); FDA Memorandum, August 15, 2002 (Doc. No. 95, Ex. 17).

[8] See, e.g., Dep. of Marvin Goldberg, June 6, 2014, at 182:22-184:6, excerpts attached as Ex. R; S. Silber, M.D. Dep. at 419 (Feb. 4, 2014)(Pl. Ex. 36)(confirming that three messages McNeil sought to convey through advertising was that Tylenol was "safe and effective," "the one doctors recommend most," and "use as directed").

OTC drugs or generic versions, as it was advertised to be.[9] She alleges that the defendants' motive for concealing information about the potentially dangerous side effects of Extra Strength Tylenol was profit-driven.[10] If the defendants had fully disclosed the risks of Extra Strength Tylenol to consumers and physicians, the plaintiff claims that her sister would not have consumed or purchased Extra Strength Tylenol.[11]

III. REGULATION OF OTC MARKETING

Extra Strength Tylenol is considered an over-the-counter (OTC) drug, meaning it can be purchased without a prescription. The Food and Drug Administration (FDA) regulates how Extra Strength Tylenol should be labeled and sold. [12] The FDA regulations regarding conditions under which acetaminophen can be taken safely are solely governed by a Tentative Final Monograph (TFM), which is a proposed rule.[13] These regulations

---

[9] See R Hayes Dep. at 39, 114, 127, 129-31, R. Hayes Dep. at 191-193, 199-200 (Doc. No. 49-10, Ex. J and Doc. No. 95, Ex. 1).

[10] See Master Compl., 13-md-2436, Doc. No. 32 at ¶ 87.

[11] See R. Hayes Dep. at 34, 214, 217-219, 222-26 (Def. Ex. J, Doc. No. 49-10).

[12] E.g., "How Drugs are Developed and Approved – OTC (Nonprescription) Drugs," http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ucm209647.htm; "How Drugs are Developed and Approved – Over-the-Counter (OTC) Drug Monograph Process," http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ucm317137.htm; Gerald Dal Pan, M.D., Director of Office of Surveillance and Epidemiology, CDER/FDA, Powerpoint, Jun. 29, 2009 (Doc. No. 95, Ex. 21).

A detailed recitation of the regulatory process and history is also included in the Declaration of Judith Jones, Ph.D. (May 20, 2015)(Doc. 49-19 to 49-28), FDA/CDER, Guidance for FDA Staff and Industry, Marketed Unapproved Drugs—Compliance Policy Guide, Sec. 440.100 Marketed New Drugs Without Approved NDAs or ANDAs, Sep. 19, 2011 (Doc. 49-20)(Ex. C attached to J. Jones Report, Def. Ex. S), the expert report of Cheryl Blume, Ph.D. (May 5, 2014)(Doc. No. 95, Ex. 26), and the Affidavit of Gerald Rachanow, Esq. (Doc. No. 95, Ex. 25). All three experts—Jones (for the defendants) and Blume and Rachanow (for the plaintiff)—have offered expert opinions about the FDA's regulatory process. Each side has filed a Daubert motion to exclude the other's opinion(s); these Daubert motions are still pending.

[13] See 21 C.F.R. § 330.10; Fed. Reg. 7820 (Apr. 20, 1972)(Doc. No. 49, Ex. T); 42 Fed. Reg. 35355 (July 8, 1977); 53 Fed. Reg. 46204, 46248 (Nov. 16, 1988). See also 21 C.F.R. §§ 310, 343, 369, 53 Fed. Reg. 46204, 46248, 46254 (Nov. 16, 1988)(TFM)(Pl's Ex. 48; Ex. C attached to Ex. 3 (Affidavit of Gerald Rachanow, Esq.)) or (Def.

have not outlined specific conditions under which acetaminophen would be generally recognized as safe and effective. "Under a TFM, manufacturers market products at their own risk and are able to make voluntary adjustments [to their product and its label] taking into account the information presented in the proposed TFM."[14]

The Federal Trade Commission (FTC) regulates whether Extra Strength Tylenol's advertising as an OTC drug is misleading. A Memorandum of Understanding between the FTC and the FDA gives the FTC "primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of . . . drugs [excluding prescription drugs]." Memorandum of Understanding Between FTC and the FDA, 36 Fed. Reg. 18539 (Sept. 16, 1971)(Doc. No. 46, Ex. D). Advertisers of OTC drugs are not limited to using FDA-approved labeling language when advertising an OTC drug for an FDA-approved purpose. Advertising for Over-the-Counter Drugs, 46 Fed. Reg. 24584 (May 1, 1981)(Doc. No. 46, Ex. E). OTC advertising is not required to list possible side effects or active ingredients of advertised drugs.[15]

Ex. J attached to Ex. S (Certification of Judith Jones, M.D., Ph.D.)); FDA letter re: FOIA request, Nov. 17, 2011 (Doc. No. 95, Ex. 4).

[14] See FDA Letter re: FOIA Request, Nov. 17, 2011 (Doc. No. 95, Ex. 4). See also E. Kuffner Dep., Mar. 18, 2011 at 8-10 (Doc. No. 95, Ex. 5)(explaining what duties a drug manufacturer has when new risks come to light in post-market surveillance); Wyeth v. Levine, 555 U.S. 555, 570-71 (2009)("[I]t has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times.")(discussed further below); McNeil letter to the FDA re: label change, Jan. 27, 1995 (Doc. No. 49, Ex. Q attached to Ex. S (Certification of Judith Jones, M.D., Ph.D.))("We believe that the language we are using in the Directions section of our labeling is acceptable since the issue has not yet been finalized in the final monograph for Internal Analgesic Products.")(debating FDA's recommendation that language in McNeil's label be changed to conform with the TFM language on dosing).

[15] See Ellen Frank, Director, Div. of Public Affairs, CDER of the FDA, Powerpoint, Jun. 29, 2009 at 179 (Doc. No. 95, Ex. 21).

The FTC looks at "whether any advertisement, taken as a whole, expressly or impliedly claims any purpose or use for which the drug in question has not been found to be safe and effective by the FDA" in deciding whether to bring administrative action against an OTC marketer. Id. The Federal Trade Commission (FTC) has never cited the defendants for violations related to Extra Strength Tylenol advertising.[16]

IV. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). A dispute is "genuine" when "a reasonable jury could return a verdict for the nonmoving party" based on the evidence in the record. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A factual dispute is "material" when it "might affect the outcome of the suit under the governing law." Id.

A party seeking summary judgment initially bears responsibility for informing the court of the basis for its motion and identifying those portions of the record that "it believes demonstrate the absence of a genuine issue of material fact." Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Where the non-moving party bears the burden of proof on a particular issue at trial, the moving party's initial Celotex burden can be met simply by demonstrating to the district court that "there is an absence of evidence to support the non-moving party's case." Id. at 325. After the moving party has met its initial burden, the adverse party's response must cite "particular parts of materials in the record,

[16] See Defendants' Statement of Material Facts, Doc. No. 49-31 at 24; Plaintiff's Statement admitting this fact. See also Dep. of Marvin Goldberg, June 6, 2014, at 182:22-184:6 (Doc. No. 49, Ex. R).

including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials." FED. R. CIV. P. 56(c)(1). Summary judgment is therefore appropriate when the non-moving party fails to rebut by making a factual showing that is "sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex, 477 U.S. at 322.

Under Rule 56 of the Federal Rules of Civil Procedure, the court must draw "all justifiable inferences" in favor of the non-moving party. Anderson, 477 U.S. at 255. The court must decide "not whether . . . the evidence unmistakably favors one side or the other but whether a fair-minded jury could return a verdict for the plaintiff on the evidence presented." Id. at 252. If the non-moving party has produced more than a "mere scintilla of evidence" demonstrating a genuine issue of material fact, then the court may not credit the moving party's "version of events against the opponent, even if the quantity of the [moving party's] evidence far outweighs that of its opponent." Big Apple BMW, Inc. v. BMW of N. Am., Inc., 974 F.2d 1358, 1363 (3d Cir. 1992).

V. PREEMPTION

The basis for this motion is purely legal. There are no facts in dispute relevant to the outcome of this motion. The defendants argue that the plaintiff's remaining claims are preempted, either expressly under 21 U.S.C. § 379r or impliedly under Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001).

Preemption is a concept based on the Supremacy Clause of the U.S. Constitution that provides a conflicting state law will be trumped by its federal counterpart. See Mut. Pharm. Co. v. Bartlett, 133 S. Ct. 2466, 2472-73 (2013)(citing U.S. Const., Art. VI, cl. 2). The Supreme Court has identified three types of preemption: express, field, and implied. Deweese v. Nat'l R.R. Passenger Corp. (Amtrak), 590 F.3d 239, 245 (3d Cir. 2009)(citations omitted). State law claims are expressly preempted if Congress indicates that conflicting state law will be trumped by the federal statute. See, e.g., 21 U.S.C. § 379r(e)(providing express preemption for certain regulations of non-prescription drugs). Field preemption "occurs when a state law impinges upon a 'field reserved for federal regulation.'" Deweese, 590 F.3d at 246 (quoting United States v. Locke, 529 U.S. 89 (2000)). Even if a federal statute does not expressly preempt a state law, the state law may be impliedly pre-empted where it is "impossible for a private party to comply with both state and federal requirements." Bartlett, 133 S. Ct. at 2473 (quoting English v. General Elec. Co., 496 U.S. 72, 79 (1990)(quotation marks omitted)).[17]

There is a general presumption against preemption. See, e.g., Deweese, 590 F.3d at 246 (citing Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992)).[18] The Third Circuit has cautioned against "lightly infer[ring]" preemption where "state compensatory regimes have traditionally played an important role." Fellner v. Tri-Union Seafoods,

[17] See also Deweese v. Nat'l R.R. Passenger Corp. (Amtrak), 590 F.3d 239, 246 (3d Cir. 2009)("[I]mplied conflict preemption exists when, 'under the circumstances of [a] particular case, [the state law] stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'")(quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)); Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142–143 (1963)("A holding of federal exclusion of state law is inescapable and requires no inquiry into congressional design where compliance with both federal and state regulations is a physical impossibility for one engaged in interstate commerce").

[18] See also Farina v. Nokia Inc., 625 F.3d 97, 116 (3d Cir. 2010).

L.L.C., 539 F.3d 237, 249 (3d Cir. 2008). Whenever possible, preemption analysis should attempt to reconcile the state law and federal law with one another. See Deweese, 590 F.3d at 248. "[S]tate tort law and other similar state remedial actions are often deemed complementary to federal regulatory regimes" and fall "squarely within the realm of traditional state regulation." Fellner, 539 F.3d at 248-49.

a. Express Preemption

The defendants argue that the plaintiff's fraud-based claims are expressly preempted under § 379r of the Food, Drug, and Cosmetic Act (FDCA). Section 379r, titled "National Uniformity of Nonprescription Drugs," expressly preempts state regulations that conflict with the FDCA. 21 U.S.C. § 379r(a). These regulations include "any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug." 21 U.S.C. § 379r(c). This section also includes a savings clause which states: "Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." 21 U.S.C. § 379r(e).

The defendants argue that the plaintiff's fraud-based claims fall within the purview of the FDCA, specifically § 379r(c). The defendants look to the FTC's decision not to impose a rule regarding OTC advertising as evidence of this conflict. The FTC decided that advertisers of OTC drugs should not be limited to FDA-approved labeling language. See Advertising for Over-the-Counter Drugs, 46 Fed. Reg. 24584 (May 1, 1981)(Doc. No. 46, Ex. E). From this, the defendants argue that the plaintiff's fraud-based state law claims would impose additional requirements on the defendants which

were not required by federal law. These fraud-based claims would thereby conflict with "different from or in addition to, or that is otherwise not identical with" the defendants' federal duties under the FDCA.[19] See 21 U.S.C. § 379r(a)(2).

The defendants go on to argue that the fraud-based claims are not "saved" from express preemption because they are not considered products liability claims under Alabama state law.[20] The defendants look to Alabama's statutory definition of "product liability action:"

> Any action brought by a natural person for personal injury, death, or property damage caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions,

[19] The defendants do not offer much more analysis than this in making their express preemption argument. Most of what they argue pertains to the inapplicability of the savings clause. From what the defendants have offered, I cannot not say that the plaintiff's fraud-based claims would necessarily impose an additional requirement that would conflict with FDCA—especially given that Extra Strength Tylenol is regulated by the TFM only, not a final rule.

[20] To support this argument, the defendants cite Kanter v. Warner-Lambert Co., 122 Cal. Rptr. 2d 72 (Cal. Ct. App. 2002); Carter v. Novartis Consumer Health, Inc., 582 F. Supp. 2d 1271 (C.D. Cal. 2008); and Mills v. Warner-Lambert Co., 581 F. Supp. 2d 772 (E.D. Tex. 2008).

Kanter found that the plaintiffs' claims were expressly preempted by § 379r but not saved because California products liability law required that a plaintiff assert a personal injury, not simply economic damages, in order to bring a claim. Kanter, 122 Cal. Rptr. 2d at 80-81. Therefore, the plaintiffs' claims were not considered to be included in the savings clause. Id. at 81 ("Plaintiffs have not alleged a cause of action under the traditional product liability law of this state, and the savings clause does not exempt their claims from preemption.").

Carter followed Kanter in finding that the plaintiffs' claims were not products liability claims under California law and, therefore, were not "saved." See Carter, 582 F. Supp. 2d at 1287 ("In concluding that those claims were not 'product liability' actions under § 379r(e), Kanter established that '[u]nder the product liability law of California, injury to the plaintiff from a defective product is an essential element of a cause of action,' and that 'if the damage consists solely of economic losses, recovery on a products liability theory is unavailable.' … This Court is obligated to follow Kanter, at least to the extent it speaks to the contours of California product liability law.").

Mills found that the plaintiffs' implied warranty of merchantability and Texas Deceptive Trade Practices Act claims were expressly preempted by § 379r because under Texas law they were not considered products liability claims that could be included in the savings clause of § 379r. Mills, 581 F. Supp. 2d at 775-776, 790-93 ("Because this is not a products liability action (under Texas law), Plaintiffs' claims are expressly barred by Section 379r of the Federal Food, Drug and Cosmetic Act, (21 U.S.C. § 301 et. seq.)(the 'FDCA'), the preemption clause of the statute that relates to nonprescription drugs."). The plaintiffs' claims, like those in Kanter and Carter, sought only economic damages and not damages caused by personal harm. Id. at 791.

These cases involve Texas and California, not Alabama, law. Unlike this case, they also did not assert personal harm related to a defective product. That point was key to the analysis about whether the preempted claims would be considered products liability claims within the savings clause. These cases are not helpful.

> marketing, packaging, or labeling of a manufactured product when such action is based upon (a) negligence, (b) innocent or negligent misrepresentation, (c) the manufacturer's liability doctrine, (d) the Alabama extended manufacturer's liability doctrine, as it exists or is hereafter construed or modified, (e) breach of any implied warranty, or (f) breach of any oral express warranty and no other. A product liability action does not include an action for contribution or indemnity.

Ala. Code § 6-5-501. The defendants focus on the words "and no other" as an indication that fraud would not be included in the list provided. This argument totally ignores Alabama's own definition of a products claim: personal injury actions based on "innocent or negligent misrepresentation" in the "marketing" of a product would be considered a "product liability action" under Alabama law. If "innocent or negligent misrepresentation" were included in what would be a "products liability action," then it would seem logical that "fraudulent misrepresentation"—a misrepresentation with a higher degree of intentionality—would also be a possible claim included in a product liability action. Nor is it much of a stretch to conclude that fraudulent misrepresentation could occur in the marketing of a product. In short, the defendants advocate for an absurd interpretation of the statute's plain language. Under the plain reading of the statute, the plaintiff's claims certainly would be included in products liability actions under Alabama law.

The defendants offer Wyeth, Inc. v. Weeks, 159 So.3d 649 (Ala. 2014), in support of their reading of "product liability action" under Alabama law. In Weeks, the Alabama Supreme Court explained that fraudulent suppression was a claim not covered by the principles of the Alabama Extended Manufacturer's Liability Doctrine (AEMLD) —

Alabama's judicially-created products liability doctrine which follows Restatement 402A.[21] Id. at 656.[22] Weeks, however, was not looking at the distinction between the two claims. Instead, its focus was on what duty a brand-name prescription drug manufacturer had to users taking a generic version of brand-name drug. Id. at 666-77. Finding that a brand-name prescription drug manufacturer had a duty to third-party users of generic drugs, the Alabama Supreme Court held that "a brand-name-drug company may be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture of a brand-name prescription drug, by a plaintiff claiming physical injury caused by a generic drug manufactured by a different company [under Alabama law]." Id. at 677.

In making its decision, the court relied heavily on the dictates of PLIVA v. Messing, 131 S.Ct. 2567 (2011), and Wyeth v. Levine, 555 U.S. 555 (2009). Id. at 659-64. Both PLIVA and Levine discussed when state-law drug products liability claims were preempted under the FDCA. Though Weeks stated fraudulent suppression was not an AEMLD-based claim, it treated it as a products liability claim for the purposes of preemption. This makes sense because the definition of "product liability action" includes claims based on the AEMLD *and* other traditional tort-based theories like negligence,

[21] In making this distinction, the Alabama Supreme Court recognized that the AEMLD does not provide the legal dictates by which a fraudulent suppression claim would be decided. See Weeks, 159 So.3d at 656 ("We have also recognized that fraudulent suppression is a claim separate from an AEMLD claim. Keck, supra. Accordingly, for purposes of this certified question, we will not treat the Weekses' claims as AEMLD claims governed by the principles of the AEMLD."). Since the fraudulent suppression claim was governed by statute while the AEMLD was judicially-created, it seems the court was recognizing the limits of its authority regarding what law could govern the fraudulent suppression claim.

[22] See Casrell v. Altec Industries, Inc., 335 So.2d 128, 131-34 (Ala.1976); Atkins v. American Motors Corp., 335 So.2d 134, 137-43 (Ala.1976)(explaining the principles of the AEMLD).

warranty, and misrepresentation.[23] See Ala. Code § 6-5-501. From Weeks, I cannot interpret the definition of "product liability action" to be as narrow as the defendants claim it is. Weeks supports the interpretation that fraud-based claims may be considered product liability claims under Alabama law for the purposes of determining preemption.

For these reasons, I find that the plaintiff's fraud-based claims are not expressly preempted by § 379r of the Food, Drug, and Cosmetic Act (FDCA) and, instead, are covered by its savings clause.

b. Implied Preemption

The defendants also argue that the plaintiff's claims are impliedly preempted by Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001). In Buckman, the plaintiffs claimed that fraudulent misrepresentations about orthopedic screws made by defendants to the FDA caused them injury when the screws did not work properly. But for the misrepresentation, the screws would not have been approved by the FDA. Buckman, 531 U.S. at 343. The fraud claims in that case stemmed solely from disclosure requirements in the FDCA, not state common law duties. Id. at 353. The Court held that fraud-on-the-FDA claims were impliedly preempted because these types of state-law tort claims conflicted with the FDCA. Id. at 348. "The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the [FDA], and that this authority is used by the Administration to achieve a somewhat

[23] See also Keck v. Dryvit Sys., Inc., 830 So.2d 1, 4-8, 10-11 (Ala. 2002)(discussing a products liability action which included AEMLD, negligence, and fraudulent suppression claims).

delicate balance of statutory objectives." Id. Allowing fraud-on-the-FDA claims, the Court reasoned, could skew that balance. Id.

Most of the plaintiff's allegations of fraud and fraudulent concealment center on the information disclosed to consumers and physicians primarily. See Compl., Doc. No. 1 at ¶¶ 93-109, 118-126.[24] However, the plaintiff does allege that the defendants concealed information from the FDA itself. See Compl., Doc. No. 1 at ¶¶ 96-97, 121.[25] To the extent that these allegations could be read as a fraud-on-the-FDA claim, they would be preempted.[26] However, viewing the plaintiff's allegations for her fraud and fraudulent suppression claims as a whole, I cannot say the plaintiff's claims are fraud-on-the-FDA claims.

Instead, the crux of the claims is that the defendants disseminated false or inaccurate information about Extra Strength Tylenol in its communications to the decedent herself and her physician, not just to the FDA. See Brasher v. Sandoz Pharm. Corp., Nos. CV–98–TMP–2648–S, CV–98–TMP–2650–S, 2001 WL 36403362, at *7 (N.D. Ala. Sept. 21, 2001)("Notwithstanding that information may have been misrepresented to or concealed from the FDA, once defendant undertook to misrepresent those facts to plaintiff, or to conceal from plaintiff facts it was bound to disclose, the plaintiff's claim no longer rests simply on the assertion that the agency was defrauded but on the additional fact that she was defrauded."). These claims are different from those

[24] See also Master Compl., 13-md-2436, Doc. No. 32 at ¶¶ 86-100, 107-119.

[25] See also Master Compl., 13-md-2436, Doc. No. 32 at ¶¶ 89, 90, 110.

[26] Whether evidence of fraudulent statements to the FDA can be admitted into evidence is covered by a separate motion in limine still pending before the court.

asserted in Buckman. See id. (denying motion for summary judgment on plaintiff's fraud, suppression, and misrepresentation claims based on Buckman preemption because Supreme Court only addressed fraud-on-the FDA claims in Buckman and no other claims were asserted in that action). They are not based simply on some regulatory duty owed to the FDA, the breach of which caused injury to the decedent.[27] They are based on a duty found in Alabama's state law regarding fraudulent misrepresentation.[28] See Ala. Code § 6-5-101.[29] See also Weeks, 159 So.3d at 656 ("An essential element of fraudulent-misrepresentation and fraudulent-suppression claims is a duty to disclose." (quoting Nesbitt v. Frederick, 941 So.2d 950, 955 (Ala. 2006)).

Beyond arguing preemption under Buckman, the defendants offer no other reasons why it was impossible for them to comply with both their state law duties and their federal law duties under the FDCA. "Impossibility pre-emption is a demanding defense." Wyeth v. Levine, 555 U.S. 555, 573 (2009). The defendants have not met their burden in

[27] See Jackson v. GlaxoSmithKline, LLC, No. 1:12–cv–2372, 2013 WL 5408456, at *7 (M.D. Pa. Sept. 25, 2013)(dismissing *pro se* litigant's claims sua sponte under Poulis for failing to comply with court orders; determining that the claims as alleged in a "spare two-page" complaint were preempted by Buckman as stated because they the defendant violated parts of the FDCA and were not based in a private right of action); Sykes v. Glaxo-Smithkline, 484 F. Supp. 2d 289, 304-05, n. 16 (E.D. Pa. 2007)(Stengel, J.)(noting that a "state law claim based on a vaccine manufacturer's intentional withholding of information from the FDA would be preempted under the Supreme Court's decision in Buckman").

[28] See Sykes v. Glaxo-Smithkline, 484 F. Supp. 2d 289, 319, n. 34 (E.D. Pa. 2007)(Stengel, J.)("Although the plaintiffs do assert that the mercury found in HypRho–D was toxic contrary to the FDA's judgment, the crux of their claim focuses on the duty a manufacturer owes to its consumer, as opposed to any duty owed to a federal agency. See Buckman, 531 U.S. at 352–53, 121 S.Ct. 1012. In other words, the plaintiffs' defective design claims are based on traditional state tort law principles.").

[29] Ala. Code § 6-5-101 states: "Misrepresentations of a material fact made willfully to deceive, or recklessly without knowledge, and acted on by the opposite party, or if made by mistake and innocently and acted on by the opposite party, constitute legal fraud." A claim of fraudulent misrepresentation comprises the following elements: "(1) a false representation (2) concerning a material fact (3) relied upon by the plaintiff (4) who was damaged as a proximate result." Weeks, 159 So.3d at 656 (quoting Fisher v. Comer Plantation, 772 So.2d 455, 463 (Ala. 2000)(quotation marks and citations omitted)).

establishing this defense. See Brown v. Johnson & Johnson, 64 F.Supp.3d 717, 721-22 (E.D. Pa. 2014)(finding that the "[d]efendants have not made out federal preemption" because the "[d]efendants have failed to meet their 'exacting burden.'").

For these reasons, I do not find the fraud and fraudulent concealment claims to be impliedly preempted.[30]

VI. CONCLUSION

For the foregoing reasons, I will deny the defendants' motion for summary judgment on the plaintiff's short form complaint (Doc. No. 46).

An appropriate Order follows.

[30] The defendants cite Henderson v. Merck & Co., No. 04-CV-05987-LDD, 2005 WL 2600220, at *10 (E.D. Pa. Oct. 11, 2005), as support for their Buckman preemption argument. Henderson was based on a conflict between Michigan law and the FDCA. Michigan law on this point differs from Alabama law. Henderson is distinguishable and not persuasive.